



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,865	07/26/2001	Richard R. Sharpe JR.	2009-174	7692
7590	05/14/2004		EXAMINER	
HOGAN & HARTSON L.L.P 500 South Grand Avenue Suite 1900 Los Angeles, CA 90071			SINES, BRIAN J	
			ART UNIT	PAPER NUMBER
			1743	
DATE MAILED: 05/14/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/915,865	SHARPE ET AL.
	Examiner	Art Unit
	Brian J. Sines	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 10/8/2003.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) 1-6 and 14-26 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 7-14 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \*    c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of group II, claims 7 – 14 in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (see MPEP § 818.03(a)).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 – 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "control apparatus" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "test" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "test run" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "subsystem base class" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "units" in line 3. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

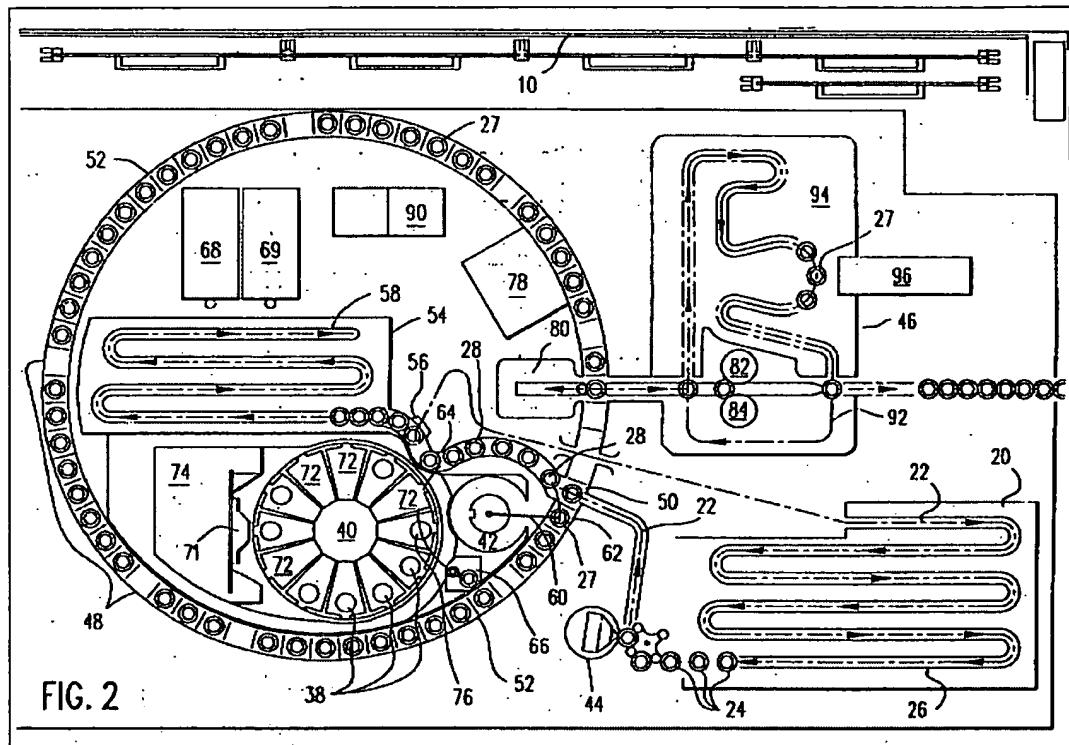
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7 – 11, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Babson *et al.* (U.S. Pat. No. 5,316,726 A). Regarding claims 7 and 13, Babson *et al.* teach an apparatus for the mechanical control of an automated immunochemistry instrument (10), which has a multiplicity of subsystems, such as a reagent carousel (40), incubation carousel (52), detection station (46) and a pipetting station (42), for performing immunochemistry assays, wherein the apparatus comprises a mechanical control system comprising a computer control apparatus (12) having both object-oriented features and real-time features for controlling the operations of a multiplicity of subsystems, which perform various operations, such as incubation, solution mixing, aspiration, reagent addition and sample detection, during the performance of an immunoassay. Babson *et al.* teach that the object-oriented features include a feature, such as the computer control apparatus, for causing specific actions, such as incubation, solution mixing,

aspiration, reagent addition or detection, to be performed on specific vessels, or unique assay tubes, at specific times during the performance of an immunoassay (see col. 2, lines 41 – 68 & col. 3, lines 1 – 6; figures 1 – 3 & 7 – 9). The computer control apparatus also tracks the progress of each immunoassay being performed in the analyzer in real-time (see col. 3, lines 1 – 6).



Regarding claims 8 and 9, Babson *et al.* teach that the computer control apparatus incorporates the use of a sequencing, scheduling or timing function (see col. 2, lines 57 – 68 & col. 3, lines 1 – 6). Regarding claim 10, Babson *et al.* teach that the computer control apparatus (12) comprises a recipe or computer algorithm containing instructions for enabling the instrument to perform each assay (see col. 7, lines 10 – 29). Regarding claim 11, Babson *et al.* teach that the computer control apparatus comprises a chronicle or table, which stores test history information, such as sample concentrations, pertaining to each assay run (see col. 11, lines 59 – 65). Regarding claim 14, Babson *et al.* teach that the apparatus includes a feature, which can be

regarded as the computer control apparatus, for satisfying the requirement that the specific actions, such as incubation, mixing or washing, performed by each of the subsystems must occur at a specific time in order for the apparatus to function correctly (see col. 2, lines 41 – 68 & col. 3, lines 1 – 6).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Babson *et al.* in view of Kristoff *et al.* (U.S. Pat. No. 6,128,542 A). As previously discussed, Babson *et al.* teach that a computer algorithm is used to operate the analyzer instrument in performing the immunoassay analyses. However, Babson *et al.* do not specifically teach that the object-oriented features include the feature of hiding the real-time features in a subsystem base class. Kristoff *et al.* do teach the use of information hiding or encapsulation in a computer algorithm, which utilizes object-oriented database programming techniques, for controlling factory

machinery (see col. 4, lines 22 – 44). Kristoff *et al.* teach that their disclosed invention is “equally applicable to all instruction-driven machines” (see col. 6, lines 3 – 9). Kristoff *et al.* further teach the use of class instances (e.g., the use of a subsystem base class) (see col. 2, lines 1 – 8 & col. 5, lines 31 – 65). Kristoff *et al.* teach that their disclosed invention affords more flexibility in changing programmed machine executable steps (see col. 4, lines 22 – 44). Consequently, a person of ordinary skill in the art would have recognized the suitability of incorporating the teachings of Kristoff *et al.* with the operation of the apparatus, as taught by Babson *et al.*, for the intended purpose of facilitating effective apparatus control having both object-oriented features and real-time features (see MPEP § 2144.07). Furthermore, the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Hence, in consideration of the prior art teachings, the determination of obviousness requires only a reasonable expectation of success (see MPEP § 2143.02). Kristoff *et al.* do effectively demonstrate the use of information hiding or encapsulation in a computer algorithm, which utilizes object-oriented database programming techniques, in controlling an instruction-driven apparatus (see col. 4, lines 22 – 44). Accordingly, a person of ordinary skill in the art would have had a reasonable expectation of success of incorporating the use of such an encapsulation or hiding feature in a computer control algorithm in the control of an analyzer apparatus, as taught by Babson *et al.*, which also utilizes object-oriented features. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of hidden real-time features, as taught by Kristoff *et al.*, with the

apparatus, as taught by Babson *et al.*, in order to facilitate the effective operation of the apparatus in performing the immunoassay analyses.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Choperena *et al.* teach an automated chemical analyzer. The disclosed invention provides an apparatus and method for efficiently scheduling and performing analytical tests, including immunoassays, on samples. Sugawara *et al.* teach an automated synthesis apparatus and method for controlling the apparatus. Iwahashi *et al.* teach an automatic immunoassay method and apparatus. Wang *et al.* teach computer programs and computer-implemented methods for monitoring the progress and properties of parallel chemical reactions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (703) 305-0401. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700